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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,230	04/02/2004	Victor I. Chornenky	1004.013	3048
7590	03/31/2006		EXAMINER	
Law Offices P.O. Box 386353 Bloomington, MN 55438			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/817,230

Applicant(s)

CHORNENKY ET AL.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention I: claims 1-14 and Species I: Figure 1 with claims 1-8 readable thereon and the cancellation of claims 15-26 in the reply filed on 3/9/2006 is acknowledged. Claims 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Drawings

2. The drawings are objected to because copy machine marks are not accepted and the lines, numbers, and letters in Figs 1-11 are not uniformly thick and well defined. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: In paragraph 53, In 6 the Applicant recited that reference number (62) is an "eyelid"; however, as shown in Figure 1 the reference number (62) does not reference to an eyelid and instead appears to reference a curved portion of the hollow probe.

Appropriate correction is required.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Apparatus for treatment of macular degeneration.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Weiss (6402734). Weiss discloses a minimally invasive therapeutic agent delivery system (Fig 4) comprising a reservoir (12) comprising a therapeutic agent (col 4, In 14); an elongate

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probe (6) having a passage therein configured to conform at least in part to the curvature of the eye (col 3, Ins 50-64) and has a proximal probe end (Fig 3) and a distal probe end (Fig 3) including a distal probe opening (Fig 3); a therapeutic agent delivery apparatus (4) being fluidly connected to said reservoir (Fig 4; col 3, Ins 50-64; col 4, Ins 11-21) and configured to be disposed within said passage (Fig 3) and movable between a retracted inoperative position within said probe (col 3, Ins 50-64) and an extended operational position (col 3, Ins 50-64), wherein movement of said delivery apparatus from the inactive to the operational position enables the therapeutic agents to be dispensed from said reservoir through said distal probe opening into the eye (col 3, Ins 50-64; col 4, Ins 11-21; col 5, Ins 23-38); a handle (1a) attached to said probe proximal end (Fig 1); the reservoir being attached to said handle (Fig 4); the therapeutic agent delivery apparatus comprises an elongate needle (4; col 3, Ins 21-32).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaleski (5242449) in view of Yaacobi et al (6413245). Zaleski discloses a minimally invasive therapeutic agent delivery system (11) comprising a reservoir (77) comprising a therapeutic agent (col 1, Ins 15-23); an elongate probe (27) and has a proximal probe end (37; Fig 2) and a distal probe end (29; Fig 2) including a distal probe opening (33;

Fig 2); a therapeutic agent delivery apparatus (37) being fluidly connected to said reservoir (Fig 1, 2) and configured to be disposed within said passage (Fig 2) and movable between a retracted inoperative position within said probe (Fig 2) and an extended operational position (Fig 3), wherein movement of said delivery apparatus from the inactive to the operational position enables the therapeutic agents to be dispensed from said reservoir through said distal probe opening into the eye (col 6, lns 43-61; col 9, lns 19-33; col 12, lns 28-39 & lns 49-51); a handle (47) attached to said probe proximal end; the reservoir being attached to said handle (77; 47; Fig 1); the therapeutic agent delivery apparatus comprises an elongate needle (29); wherein said passage bends said needle (col 5, lns 25-28) when said needle is moved from its retracted to its extended position (Fig 2, 3, 6); and said probe includes a probe positioning portion (29) at said distal probe end.

9. However, Zaleski does not disclose the elongate probe having a passage therein configured to conform at least in part to the curvature of the eye and the probe distal end having an eye-surface engaging surface configured to conform to the surface of the eye with the probe passage including a portion conforming to the surface of the eye and a portion that angles toward the eye such that said distal probe opening is in said eye-surface engaging surface.

10. Yaacobi et al teaches that it is known to have the elongate probe (58) having a passage therein configured to conform at least in part to the curvature of the eye (52, Fig 2) and the probe distal end having an eye-surface engaging surface (52, Fig 2) configured to conform to the surface of the eye with the probe passage including a

portion conforming to the surface of the eye (52) and a portion that angles toward the eye (64) such that said distal probe opening is in said eye-surface engaging surface (64, Fig 2) for the purpose of delivering ophthalmically acceptable pharmaceutically active agents to the back of the eye proximate to the macula (col 1, lns 8-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the probe as taught by Zaleski with the eye-conforming probe as taught by Yaacobi et al for the purpose of delivering ophthalmically acceptable pharmaceutically active agents to the back of the eye proximate to the macula (col 1, lns 8-14).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert



MICHAEL J. HAYES
PRIMARY EXAMINER